

James R. Condo (#005867)
Amanda Sheridan (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
JCondo@swlaw.com
ASheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Facsimile: (404) 322-6050
Richard.North@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

JOJI TAKADA, Trustee in Bankruptcy for
John Noonan; JOHN NOONAN,

Plaintiff,

Case No. CV-15-1885-PHX-DGC

v.

C. R. Bard, Inc., a New Jersey Corporation;
and Bard Peripheral Vascular Inc., an
Arizona Corporation,

Defendants.

**ANSWER AND DEFENSES OF
DEFENDANTS, C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC. AND DEMAND FOR TRIAL BY
JURY**

1 Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”)
2 (collectively “Defendants”) hereby file their answer and defenses to the Plaintiffs’ Complaint
3 (the “Complaint”) as follows:

4 **THE PARTIES**

5 1. Defendants are without information sufficient to form a belief as to the truth of
6 the allegations contained in Paragraph 1 of Plaintiffs’ Complaint and, on that basis, deny
7 them. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever
8 and deny that Plaintiffs have suffered any damages whatsoever.

9 2. Defendants are without information sufficient to form a belief as to the truth of
10 the allegations contained in Paragraph 2 of Plaintiffs’ Complaint and, on that basis, deny
11 them. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever
12 and deny that Plaintiffs have suffered any damages whatsoever.

13 3. Paragraph 3 of Plaintiffs’ Complaint does not include any factual allegations
14 and, as a result, requires no response by Defendants. However, to the extent Paragraph 3
15 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is
16 expressly denied.

17 4. Defendants admit that Bard is a New Jersey Corporation and that Bard is
18 authorized to do business, and does business, in the State of Illinois, including this judicial
19 district. Defendants admit that Bard owns a facility where vena cava filters are manufactured.
20 Defendants deny any remaining allegations contained in Paragraph 4 of Plaintiffs’ Complaint.

21 5. Defendants admit that BPV is an Arizona Corporation and that BPV does
22 business in the State of Illinois. Defendants further admit that BPV designs, sells, markets,
23 and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and
24 distributed filters under the trademark G2® Express Filter System. Defendants further admit
25 that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations
26 contained in Paragraph 5 of Plaintiffs’ Complaint.

1 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
2 human health, including sometimes death. Defendants deny any remaining allegations
3 contained in Paragraph 11 of Plaintiffs' Complaint.

4 12. The allegations contained in Paragraph 12 of Plaintiffs' Complaint are
5 conclusions of law and, therefore, require no response. To the extent that a response is
6 required, Defendants deny the allegations contained in Paragraph 12 of Plaintiffs' Complaint.

7 13. Defendants deny the allegations contained in Paragraph 13 of Plaintiffs'
8 Complaint.

9 14. Defendants admit that patients at a high risk for developing deep vein
10 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
11 including but not limited to the medications listed in Paragraph 14 of Plaintiffs' Complaint.
12 Defendants further admit that inferior vena cava filters may also be used to treat patients who
13 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
14 lack knowledge or information sufficient to form a belief as to the truth of any remaining
15 allegations contained in Paragraph 14 of Plaintiffs' Complaint and, on that basis, deny them.

16 15. Defendants lack knowledge or information or information sufficient to form a
17 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
18 were first introduced on the market. Defendants also lack knowledge or information
19 sufficient to form a belief as to the truth of the allegation regarding the time frame when
20 optional or retrievable filters came to be marketed or the other allegations regarding optional
21 or retrievable filters marketed by other manufacturers. Defendants deny any remaining
22 allegations contained in Paragraph 15 of Plaintiffs' Complaint.

23 16. Defendants admit that Bard has distributed the Simon Nitinol Filter in the
24 United States since at least 1992, that the Simon Nitinol Filter has an excellent safety record,
25 that the Simon Nitinol Filter is still in distribution, and that the Simon Nitinol Filter is only
26 indicated for permanent use. Defendants further admit that the Recovery® Filter was cleared
27
28

1 by the FDA for optional use as a retrievable inferior vena cava filter. Defendants deny any
2 remaining allegations contained in Paragraph 16 of Plaintiffs' Complaint.

3 17. Defendants deny the allegations contained in Paragraph 17 of Plaintiffs'
4 Complaint.

5 18. Defendants deny the allegations contained in Paragraph 18 of Plaintiffs'
6 Complaint as stated.

7 19. Defendants deny the allegations contained in Paragraph 19 of Plaintiffs'
8 Complaint as stated.

9 20. Defendants admit that the Recovery® Filter was cleared by the FDA for
10 permanent placement on November 27, 2002, pursuant to an application submitted under
11 Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the
12 requirements of Section 510(k) are legal conclusions of law to which no answer is required.
13 Defendants deny any remaining allegations contained in Paragraph 20 of Plaintiffs'
14 Complaint, including all sub-parts thereof and any allegations contained in Footnote 1.

15 21. Defendants admit that the Recovery® Filter was cleared by the FDA for
16 retrievable placement on July 25, 2003, pursuant to an application submitted under Section
17 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations
18 contained in Paragraph 21 of Plaintiffs' Complaint.

19 22. Defendants deny the allegations contained in Paragraph 22 of Plaintiffs'
20 Complaint.

21 23. Defendants deny the allegations contained in Paragraph 23 of Plaintiffs'
22 Complaint.

23 24. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
24 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
25 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
26 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
27 allegations contained in Paragraph 24 of Plaintiffs' Complaint.
28

1 25. Defendants admit that the Recovery® Filter was designed to be inserted
2 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
3 delivered via an introducer sheath, which is included in the delivery system for the device.
4 Defendants deny any remaining allegations of Paragraph 25 of Plaintiffs' Complaint.

5 26. Defendants admit that, as part of their continuing efforts to constantly evaluate
6 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
7 continually striving to evaluate and, if possible, improve the life-saving performance of those
8 devices. The Recovery® Filter was developed in furtherance of those efforts. Defendants
9 deny the remaining allegations contained in Paragraph 26 of Plaintiffs' Complaint, including
10 all sub-parts thereof.

11 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiffs'
12 Complaint.

13 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiffs'
14 Complaint.

15 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiffs'
16 Complaint as stated, including all subparts thereof.

17 30. Defendants deny the allegations contained in Paragraph 30 of Plaintiffs'
18 Complaint.

19 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiffs'
20 Complaint.

21 32. Defendants lack knowledge or information or information sufficient to form a
22 belief as to the truth of the allegation regarding physicians' expectations regarding
23 performance of inferior vena cava filters and, therefore, deny them. Defendants deny any
24 remaining allegations contained in Paragraph 32 of Plaintiffs' Complaint, as stated, including
25 all subparts thereof.

26 33. Defendants lack knowledge or information or information sufficient to form a
27 belief as to the truth of the allegation regarding physicians' expectations regarding
28

1 performance of inferior vena cava filters and, therefore, deny them. Defendants deny any
2 remaining allegations contained in Paragraph 33 of Plaintiffs' Complaint, as stated, including
3 all subparts thereof.

4 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiffs'
5 Complaint.

6 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiffs'
7 Complaint.

8 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiffs'
9 Complaint as stated, including all subparts thereof.

10 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiffs'
11 Complaint.

12 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiffs'
13 Complaint.

14 39. Defendants admit that, as part of their continuing efforts to constantly evaluate
15 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
16 continually striving to evaluate and, if possible, improve the life-saving performance of those
17 devices. Defendants deny the remaining allegations contained in Paragraph 39 of Plaintiffs'
18 Complaint as stated.

19 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiffs'
20 Complaint.

21 41. Defendants deny the allegations contained in Paragraph 41 of Plaintiffs'
22 Complaint.

23 42. Defendants admit that, as part of their continuing efforts to constantly evaluate
24 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
25 continually striving to evaluate and, if possible, improve the life-saving performance of those
26 devices. Defendants deny the remaining allegations contained in Paragraph 42 of Plaintiffs'
27 Complaint.

1 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiffs'
2 Complaint.

3 44. Defendants admit that caval distension is known to occur. Defendants deny any
4 remaining allegations contained in Paragraph 44 of Plaintiffs' Complaint.

5 45. Defendants admit that, as part of their continuing efforts to constantly evaluate
6 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
7 continually striving to evaluate and, if possible, improve the life-saving performance of those
8 devices. The G2® Filter was designed in furtherance of those efforts. Defendants deny the
9 remaining allegations contained in Paragraph 45 of Plaintiffs' Complaint.

10 46. Defendants admit the G2® Filter System was cleared by the United States Food
11 and Drug Administration pursuant to an application submitted under Section 510(k) of the
12 Food, Drug and Cosmetic Act in 2005. Defendants admit that the G2® Filter was originally
13 cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was
14 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.
15 Defendants deny any remaining allegations contained in Paragraph 46 of Plaintiffs'
16 Complaint.

17 47. Defendants admit that certain marketing materials for the G2® Filter contained
18 the words "enhanced fracture resistance," "improved centering," and "increased migration
19 resistance." Defendants deny any remaining allegations contained in Paragraph 47 of
20 Plaintiffs' Complaint.

21 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiffs'
22 Complaint.

23 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiffs'
24 Complaint as stated.

25 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiffs'
26 Complaint as stated.

1 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiffs'
2 Complaint.

3 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiffs'
4 Complaint as stated.

5 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiffs'
6 Complaint.

7 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiffs'
8 Complaint as stated, including all subparts thereof.

9 55. Defendants admit the G2® Express Filter System was cleared by the United
10 States Food and Drug Administration pursuant to an application submitted under Section
11 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants further admit that the G2®
12 and G2® Express Filters are similarly designed, except that the G2® Express Filter was
13 equipped with a snarable “hook” to allow retrievable via a snare device. Defendants deny any
14 remaining allegations contained in Paragraph 55 of Plaintiffs’ Complaint.

15 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiffs'
16 Complaint.

17 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiffs'
18 Complaint, including all subparts thereof.

19 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiffs'
20 Complaint.

21 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiffs'
22 Complaint.

23 60. Defendants admit that Bard received a warning letter from the FDA’s Los
24 Angeles District Office dated July 13, 2015. Defendants deny the remaining allegations of
25 Paragraph 60 of Plaintiffs’ Complaint.

26 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiffs'
27 Complaint as stated.

1 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiffs'
2 Complaint as stated.

3 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiffs'
4 Complaint.

5 64. Defendants are without knowledge or information sufficient to form a belief as
6 to the truth of the allegations regarding the trade name of any inferior vena cava filter
7 implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining
8 allegations contained in Paragraph 64 of Plaintiffs' Complaint.

9 65. Defendants are without knowledge or information sufficient to form a belief as
10 to the truth of the allegations regarding the reason why any inferior vena cava filter was
11 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
12 allegations contained in Paragraph 65 of Plaintiffs' Complaint.

13 66. Defendants are without knowledge or information sufficient to form a belief as
14 to the truth of the allegations regarding the trade name of any inferior vena cava filter
15 implanted in Plaintiff and, on that basis, deny them. Defendants admit that Bard owns a
16 facility where vena cava filters are manufactured. Defendants further admit that BPV designs,
17 sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold,
18 marketed, and distributed filters under the trademark G2® Express Filter System. Defendants
19 deny any remaining allegations contained in Paragraph 66 of Plaintiffs' Complaint.

20 67. Defendants are without knowledge or information sufficient to form a belief as
21 to the truth of the allegations contained in Paragraph 67 of Plaintiffs' Complaint and,
22 therefore, deny them. Defendants deny any remaining allegations contained in Paragraph 67
23 of Plaintiffs' Complaint.

24 68. Defendants deny the allegations contained in Paragraph 68 of Plaintiffs'
25 Complaint.

26 69. Defendants deny the allegations contained in Paragraph 69 of Plaintiffs'
27 Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of Plaintiffs' Complaint.

72. Defendants deny the allegations contained in Paragraph 72 of Plaintiffs' Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of Plaintiffs' Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiffs' Complaint.

COUNT I

NEGLIGENCE

76. Defendants incorporate by reference their responses to Paragraphs 1-75 of Plaintiffs' Complaint as if fully set forth herein.

77. Defendants deny the allegations of Paragraph 77 of Plaintiffs' Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery® and G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 78 of Plaintiffs' Complaint.

79. The allegations contained in Paragraph 79 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiffs' Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiffs' Complaint, including all sub-parts thereof.

82. Defendants deny the allegations contained in Paragraph 82 of Plaintiffs' Complaint.

83. Defendants deny the allegations contained in Paragraph 83 of Plaintiffs' Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiffs' Complaint, including all sub-parts thereof.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiffs' Complaint.

COUNT II

STRICT LIABILITY – FAILURE TO WARN

86. Defendants incorporate by reference their responses to Paragraphs 1-85 of Plaintiffs' Complaint as if fully set forth herein.

87. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System.

1 Defendants deny any remaining allegations contained in Paragraph 87 of Plaintiffs'
2 Complaint.

3 88. Defendants deny the allegations contained in Paragraph 88 of Plaintiffs'
4 Complaint.

5 89. Defendants deny the allegations contained in Paragraph 89 of Plaintiffs'
6 Complaint.

7 90. Defendants deny the allegations contained in Paragraph 90 of Plaintiffs'
8 Complaint.

9 91. Defendants deny the allegations contained in Paragraph 91 of Plaintiffs'
10 Complaint.

11 92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs'
12 Complaint.

13 93. Defendants deny the allegations contained in Paragraph 93 of Plaintiffs'
14 Complaint.

15 94. Defendants deny the allegations contained in Paragraph 94 of Plaintiffs'
16 Complaint.

17 95. Defendants deny the allegations contained in Paragraph 95 of Plaintiffs'
18 Complaint.

19 96. Defendants deny the allegations contained in Paragraph 96 of Plaintiffs'
20 Complaint.

21 97. Defendants deny the allegations contained in Paragraph 97 of Plaintiffs'
22 Complaint.

23 98. Defendants deny the allegations contained in Paragraph 98 of Plaintiffs'
24 Complaint.

25 99. Defendants deny the allegations contained in Paragraph 99 of Plaintiffs'
26 Complaint.

1 100. Defendants deny the allegations contained in Paragraph 100 of Plaintiffs'
2 Complaint.

3 101. Defendants deny the allegations contained in Paragraph 101 of Plaintiffs'
4 Complaint.

5 **COUNT III**

6 **STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

7 102. Defendants incorporate by reference their responses to Paragraphs 1-101 of
8 Plaintiffs' Complaint as if fully set forth herein.

9 103. Defendants are without knowledge or information sufficient to form a belief as
10 to the truth of the allegations regarding the trade name of any inferior vena cava filter
11 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
12 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
13 the trademark G2® Filter System were manufactured at that facility. Defendants further
14 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
15 designed, sold, marketed, and distributed filters under the trademark G2® Filter System.
16 Defendants deny any remaining allegations contained in Paragraph 103 of Plaintiffs'
17 Complaint.

18 104. Defendants deny the allegations contained in Paragraph 104 of Plaintiffs'
19 Complaint.

20 105. Defendants deny the allegations contained in Paragraph 105 of Plaintiffs'
21 Complaint.

22 106. Defendants deny the allegations contained in Paragraph 106 of Plaintiffs'
23 Complaint.

24 107. Defendants deny the allegations contained in Paragraph 107 of Plaintiffs'
25 Complaint.

26 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiffs'
27 Complaint.

1 109. Defendants deny the allegations contained in Paragraph 109 of Plaintiffs'
2 Complaint.

3 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiffs'
4 Complaint.

5 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiffs'
6 Complaint.

7 **COUNT IV**

8 **STRICT LIABILITY – MANUFACTURING DEFECT**

9 112. Defendants incorporate by reference their responses to Paragraphs 1-111 of
10 Plaintiffs' Complaint as if fully set forth herein.

11 113. Defendants are without knowledge or information sufficient to form a belief as
12 to the truth of the allegations regarding the trade name of any inferior vena cava filter
13 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
14 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
15 the trademark G2® Filter System were manufactured at that facility. Defendants further
16 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
17 designed, sold, marketed, and distributed filters under the trademark G2® Filter System.
18 Defendants deny any remaining allegations contained in Paragraph 113 of Plaintiffs'
19 Complaint.

20 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiffs'
21 Complaint.

22 115. Defendants deny the allegations contained in Paragraph 115 of Plaintiffs'
23 Complaint.

24 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiffs'
25 Complaint.

26 117. Defendants deny the allegations contained in Paragraph 117 of Plaintiffs'
27 Complaint.

COUNT V

BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

118. Defendants incorporate by reference their responses to Paragraphs 1-117 of Plaintiffs' Complaint as if fully set forth herein.

119. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 119 of Plaintiffs' Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs' Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs' Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiffs' Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of Plaintiffs' Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiffs' Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiffs' Complaint.

COUNT VI

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

128. Defendants incorporate by reference their responses to Paragraphs 1-127 of Plaintiffs' Complaint as if fully set forth herein.

129. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiffs' Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiffs' Complaint, including all sub-parts thereof.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiffs' Complaint.

134. Defendants deny the allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of Plaintiffs' Complaint.

COUNT VII

FRAUDULENT CONCEALMENT

137. Defendants incorporate by reference their responses to Paragraphs 1-136 of Plaintiffs' Complaint as if fully set forth herein.

138. Defendants deny the allegations contained in Paragraph 138 of Plaintiffs' Complaint.

139. Defendants deny the allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. Defendants deny the allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of Plaintiffs' Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Defendants deny the allegations contained in Paragraph 144 of Plaintiffs' Complaint.

145. Defendants deny the allegations contained in Paragraph 145 of Plaintiffs' Complaint.

146. The allegations contained in Paragraph 146 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants deny the allegations contained in Paragraph 147 of Plaintiffs' Complaint.

COUNT XIII

NEGLIGENT MISREPRESENTATION

148. Defendants incorporate by reference their responses to Paragraphs 1-147 of Plaintiffs' Complaint as if fully set forth herein.

149. Defendants deny the allegations contained in Paragraph 149 of Plaintiffs' Complaint, including all sub-parts thereof.

150. Defendants deny the allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants deny the allegations contained in Paragraph 151 of Plaintiffs' Complaint.

152. Defendants deny the allegations contained in Paragraph 152 of Plaintiffs' Complaint.

153. Defendants deny the allegations contained in Paragraph 153 of Plaintiffs' Complaint.

154. Defendants deny the allegations contained in Paragraph 154 of Plaintiffs' Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of Plaintiffs' Complaint.

156. Defendants deny the allegations contained in Paragraph 156 of Plaintiffs' Complaint.

COUNT IX

FRAUDULENT MISREPRESENTATIONS AS TO BARD

157. Defendants incorporate by reference their responses to Paragraphs 1-156 of Plaintiffs' Complaint as if fully set forth herein.

158. Defendants deny the allegations contained in Paragraph 158 of Plaintiffs' Complaint.

1 159. Defendants deny the allegations contained in Paragraph 159 of Plaintiffs'
2 Complaint, including all sub-parts thereof.

3 160. Defendants deny the allegations contained in Paragraph 160 of Plaintiffs'
4 Complaint.

5 161. Defendants deny the allegations contained in Paragraph 161 of Plaintiffs'
6 Complaint.

7 162. Defendants deny the allegations contained in Paragraph 162 of Plaintiffs'
8 Complaint.

9 163. Defendants deny the allegations contained in Paragraph 163 of Plaintiffs'
10 Complaint.

11 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiffs'
12 Complaint.

13 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiffs'
14 Complaint.

15 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiffs'
16 Complaint.

17 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiffs'
18 Complaint.

19 168. Defendants deny the allegations contained in Paragraph 168 of Plaintiffs'
20 Complaint.

21 169. Defendants deny the allegations contained in Paragraph 169 of Plaintiffs'
22 Complaint.

23 170. Defendants deny the allegations contained in Paragraph 170 of Plaintiffs'
24 Complaint.

25 171. Defendants deny the allegations contained in Paragraph 171 of Plaintiffs'
26 Complaint.

PUNITIVE DAMAGES AS TO BARD

172. Defendants incorporate by reference their responses to Paragraphs 1-171 of Plaintiffs' Complaint as if fully set forth herein.

173. Defendants deny the allegations contained in Paragraph 173 of Plaintiffs' Complaint.

174. Defendants deny the allegations contained in Paragraph 174 of Plaintiffs' Complaint, including all subparts thereof.

175. Defendants deny the allegations contained in Paragraph 175 of Plaintiffs' Complaint.

176. Defendants deny the allegations contained in Paragraph 176 of Plaintiffs' Complaint.

PRAYER FOR DAMAGES

Furthermore, responding to the unnumbered Paragraph, including sub-parts numbered 1 through 4, following the heading "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Further, responding to the prayer for relief as to the first cause of action for negligence against Defendants Bard and BPV, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

Further, responding to the prayer for relief as to the second cause of action for strict liability – failure to warn against Defendants Bard and BPV, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

Further, responding to the prayer for relief as to the third cause of action for strict liability – design defect against Defendants Bard and BPV, including sub-parts numbered 1

1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts.
2 Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

3 Further, responding to the prayer for relief as to the fourth cause of action for strict
4 liability – manufacturing defect against Defendants Bard and BPV, including sub-parts
5 numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-
6 parts. Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

7 Further, responding to the prayer for relief as to the fifth cause of action for breach of
8 express warranty of merchantability against Defendants Bard and BPV, including sub-parts
9 numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-
10 parts. Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

11 Further, responding to the prayer for relief as to the sixth cause of action for breach of
12 implied warranty of merchantability against Defendants Bard and BPV, including sub-parts
13 numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-
14 parts. Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

15 Further, responding to the prayer for relief as to the seventh cause of action for
16 fraudulent concealment against Defendants Bard and BPV, including sub-parts numbered 1
17 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts.
18 Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

19 Further, responding to the prayer for relief as to the eighth cause of action for
20 negligent misrepresentation against Defendants Bard and BPV, including sub-parts numbered
21 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts.
22 Defendants deny that Plaintiffs are entitled to any relief requested in the Complaint.

23 Further, responding to the prayer for relief as to the ninth cause of action for fraudulent
24 misrepresentation against Defendants Bard and BPV, including sub-parts numbered 1 through
25 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants
26 deny that Plaintiffs are entitled to any relief requested in the Complaint.

27 Defendants further deny each and every allegation not specifically admitted herein.
28

DEFENSES AND AFFIRMATIVE DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs is barred to the extent Plaintiff voluntarily exposed himself to a known risk and/or failed to mitigate his alleged damages. To the extent Plaintiff has failed to mitigate his alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

6. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

1 8. If Plaintiffs have been damaged, which Defendants deny, such damages were
2 caused by unforeseeable, independent, intervening, and/or superseding events for which
3 Defendants are not legally responsible.

4 9. There was no defect in the product at issue with the result that Plaintiffs are not
5 entitled to recover against Defendants in this cause.

6 10. If there were any defect in the products – and Defendants deny that there were
7 any defects – nevertheless, there was no causal connection between any alleged defect and
8 the product on the one hand and any damage to Plaintiffs on the other with the result that
9 Plaintiffs are not entitled to recover against Defendants in this cause.

10 11. Plaintiffs' injuries, losses, or damages, if any, were caused by or contributed to
11 by other persons or entities that are severally liable for all or part of Plaintiffs' alleged
12 injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is
13 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
14 either in whole or in part, from all persons or entities whose negligence or fault proximately
15 caused or contributed to cause Plaintiffs' alleged damages.

16 12. Plaintiffs' claims are barred to the extent that the injuries alleged in the
17 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a
18 manner not intended by Defendants and over which Defendants had no control.

19 13. Plaintiffs' claims are barred to the extent that the injuries alleged in the
20 Complaint were caused by a substantial change in the product after leaving the possession,
21 custody, and control of Defendants.

22 14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not
23 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
24 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
25 Defendants.

26 15. Plaintiffs' claims for breach of implied warranty must fail because the product
27 was not used for its ordinary purpose.
28

1 16. Defendants neither had nor breached any alleged duty to warn with respect to
2 the product, with the result that Plaintiffs are not entitled to recover in this cause.

3 17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate
4 warnings and instructions to learned intermediaries.

5 18. At all relevant times, herein, Plaintiffs' physicians were in the position of
6 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
7 benefits of the subject product.

8 19. If Plaintiffs have been damaged, which Defendants deny, the actions of persons
9 or entities for whose conduct Defendants are not legally responsible and the independent
10 knowledge of these persons or entities of the risks inherent in the use of the product and other
11 independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged
12 damages.

13 20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in
14 Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical
15 conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were
16 unknown, unknowable, or not reasonably foreseeable to Defendants.

17 21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of
18 the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and
19 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
20 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
21 damages that Plaintiffs seek to recover herein.

22 22. At all relevant times during which the device at issue was designed, developed,
23 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
24 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
25 information, and instructions, all pursuant to generally recognized prevailing industry
26 standards and state-of-the-art in existence at the time.

1 23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as
2 a result of the alleged conduct and do not have any right, standing, or competency to maintain
3 claims for damages or other relief.

4 24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver,
5 estoppel, and/or laches.

6 25. If Plaintiffs suffered any damages or injuries, which are denied, Defendants
7 state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the
8 doctrines of contributory and/or comparative negligence.

9 26. In the further alternative, and only in the event that it is determined that
10 Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion
11 to the degree or percentage of negligence, fault or exposure to products attributable to
12 Plaintiff, any other defendants, third-party defendants, or other persons, including any party
13 immune because bankruptcy renders them immune from further litigation, as well as any
14 party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the
15 future.

16 27. Should Defendants be held liable to Plaintiffs, which liability is specifically
17 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs
18 from all collateral sources.

19 28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery
20 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
21 claims, and the prohibition on double recovery for the same injury.

22 29. The injuries and damages allegedly sustained by Plaintiffs may be due to the
23 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
24 over which Defendants had no control.

25 30. The conduct of Defendants and all activities with respect to the subject product
26 have been and are under the supervision of the Federal Food and Drug Administration
27 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive
28

1 relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative
2 remedies.

3 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
4 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
5 their Answer to file such further pleadings as are necessary to preserve and assert such
6 defenses, claims, credits, offsets, or remedies.

7 32. The device at issue complied with any applicable product safety statute or
8 administrative regulation, and therefore Plaintiffs' defective design and warnings-based
9 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
10 comments thereto.

11 33. Plaintiffs cannot show that any reasonable alternative design would have
12 rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiffs' Complaint to
13 be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could
14 Defendants have known of any alternative design that may be identified by Plaintiffs.

15 34. The device at issue was not sold in a defective condition unreasonably
16 dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the
17 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
18 comparable provisions of the Restatement (Third) of Torts (Products Liability).

19 35. At all relevant times during which the device at issue was designed, developed,
20 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
21 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
22 information, and instructions, all pursuant to generally recognized prevailing industry
23 standards and state-of-the-art in existence at the time.

24 36. Defendants specifically plead all affirmative defenses under the Uniform
25 Commercial Code ("UCC") now existing or which may arise in the future, including those
26 defenses provided by UCC §§ 2-607 and 2-709.

1 37. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to
2 by other persons or entities that are severally liable for all or part of Plaintiffs' alleged
3 injuries, losses or damages. Defendants request apportionment of fault.

4 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
5 grossly negligent, and, therefore, any award of punitive damages is barred.

6 39. To the extent the claims asserted in Plaintiffs' Complaint are based on a theory
7 providing for liability without proof of defect and proof of causation, the claims violate
8 Defendants' rights under the Constitution of the United States and analogous provisions of
9 the Illinois Constitution.

10 40. To the extent Plaintiffs demand punitive damages, Defendants specifically
11 incorporate by reference any and all standards of limitations regarding the determination
12 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No.*
13 *America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group,*
14 *Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513
15 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25,
16 2008) and their progeny as well as other similar cases under both federal and state law.

17 41. To the extent Plaintiffs demand punitive or exemplary damages, such damages
18 violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth
19 Amendments to the Constitution of the United States of America, and similar provisions of
20 the Illinois Constitution, on grounds including the following:

21 (a) it is a violation of the Due Process and Equal Protection Clauses of the
22 Fourteenth Amendment of the United States Constitution to impose punitive
23 damages, which are penal in nature, against a civil defendant upon the plaintiffs
24 satisfying a burden of proof which is less than the "beyond a reasonable doubt"
25 burden of proof required in criminal cases;

26 (b) the procedures pursuant to which punitive damages are awarded may result in
27 the award of joint and several judgments against multiple defendants for
28

1 different alleged acts of wrongdoing, which infringes upon the Due Process and
2 Equal Protection Clauses of the Fourteenth Amendment of the United States
3 Constitution;

4 (c) the procedures to which punitive damages are awarded fail to provide a
5 reasonable limit on the amount of the award against Defendants, which thereby
6 violates the Due Process Clause of the Fourteenth Amendment of the United
7 States Constitution;

8 (d) the procedures pursuant to which punitive damages are awarded fail to provide
9 specific standards for the amount of the award of punitive damages which
10 thereby violates the Due Process Clause of the Fourteenth Amendment of the
11 United States Constitution;

12 (e) the procedures pursuant to which punitive damages are awarded result in the
13 imposition of different penalties for the same or similar acts, and thus violate
14 the Equal Protection Clause of the Fourteenth Amendment of the United States
15 Constitution;

16 (f) the procedures pursuant to which punitive damages are awarded permit the
17 imposition of punitive damages in excess of the maximum criminal fine for the
18 same or similar conduct, which thereby infringes upon the Due Process Clause
19 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
20 Fourteenth Amendment of the United States Constitution;

21 (g) the procedures pursuant to which punitive damages are awarded permit the
22 imposition of excessive fines in violation of the Eighth Amendment of the
23 United States Constitution;

24 (h) the award of punitive damages to the plaintiffs in this action would constitute a
25 deprivation of property without due process of law; and

26 (i) the procedures pursuant to which punitive damages are awarded permit the
27 imposition of an excessive fine and penalty.
28

1 This 19th day of October, 2015.

2
3 s/Richard B. North, Jr.
4 Richard B. North, Jr.
5 Georgia Bar No. 545599
6 NELSON MULLINS RILEY & SCARBOROUGH, LLP
7 Atlantic Station
8 201 17th Street, NW / Suite 1700
9 Atlanta, GA 30363
10 PH: (404) 322-6000
11 FX: (404) 322-6050
12 Richard.North@nelsonmullins.com

13 James R. Condo (#005867)
14 Amanda Sheridan (#005867)
15 SNELL & WILMER L.L.P.
16 One Arizona Center
17 400 E. Van Buren
18 Phoenix, AZ 85004-2204
19 PH: (602) 382-6000
20 JCondo@swlaw.com
21 ASheridan@swlaw.com

22 **Attorney for Defendants C. R. Bard, Inc. and**
23 **Bard Peripheral Vascular, Inc.**
24
25
26
27
28

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 19, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
Richard.North@nelsonmullins.com